

### SUPPORT FOR THE AMENDMENT

Support for the amendment to claim 1 is found in claim 7 as originally presented and on page 6, lines 9 and 13-20 of the specification. Support for the amendments to claims 3, 4, 8, and 20 is found on page 6, lines 14-20 of the specification. Support for claims 21, 22, 32, 33, 43 and 44 is found on page 7, lines 4-6 of the specification. Support for claims 24 and 35 is found in claim 2 as originally presented. Support for claims 25 and 36 is found in claim 3 as originally presented. Support for claims 26 and 37 is found in claim 4 as originally presented. Support for claims 27 and 38 is found in claim 5 as originally presented. Support for claims 28 and 39 is found in claim 8 as originally presented. Support for claims 29 and 40 is found in claim 12 as originally presented. Support for claims 30 and 41 is found in claim 13 as originally presented. Support for claims 31 and 42 is found in claim 14 as originally presented. Claims 9-11 and 15-19 have been canceled without prejudice to their prosecution in a continuation or divisional application.

No new matter would be added to this application by entry of this amendment.

Upon entry of this amendment claims 1-5, 8, 12-14 and 20-44 will now be active in this application with claims 1-5, 8, 12-14 and 21-44 being under active consideration.

### REQUEST FOR RECONSIDERATION

The present invention is directed to a method of regulating autonomic nerve activity. Stimulation of parasympathetic activity over sympathetic activity is believed to reduce stress and calm aggravated mental states, inducing sleep. Oral and percutaneous administration of active ingredients as well as fragrances have been used to improve sleep induction. Some fragrances have been identified as disagreeable or irritating and accordingly new methods for regulating autonomic nerve activity are sought.

The present invention addresses this problem by providing a method for regulating autonomic nerve activity such as by increasing all ECG R-R interval, or decreasing systolic and/or diastolic blood pressure, by administering **by inhalation**, a terpene alcohol having a boiling point of at least 200°C, and having an odor below a detectable threshold. Applicants have discovered that administration of such terpene alcohols by inhalation is effective for regulating autonomic nerve activity. Such a method is nowhere disclosed or suggested in the cited prior art of record.

The rejections of Claims 1-14 under 35 U.S.C. § 103 over Swada and Binet et al. are respectfully traversed.

Neither of these references disclose or suggest a method of regulating autonomic nerve activity by administering by inhalation a terpene alcohol.

Binet describes an investigation into the psychosedative and spasmolytic results by orally or intravenously administering synthetic farnesol. The reference neither discloses nor suggests a method of administration by inhalation.

Sawada et al. investigates the physiological effects of volatile components in forest, such as monoterpenes. No mode of administration is disclosed by this reference and accordingly a method of regulating autonomic nerve activity by administration by inhalation can not be suggested by this reference.

In contrast, the present invention is directed to a method for regulating autonomic nerve activity, in which a terpene alcohol is administered by inhalation. Applicants note that the claims have been amended to recite the limitation of claim 7, in that the alcohol is administered by inhalation.

As the cited references fail to disclose or suggest a method in which a terpene alcohol is administered by inhalation, the present invention is clearly not obvious from these

references and accordingly withdrawal of the rejections under 35 U.S.C. § 103 is respectfully requested.

The rejection of Claims 1-14 under 35 U.S.C. § 112, first paragraph and the objection to the specification are respectfully traversed.

Applicants respectfully submit that the claimed invention described in sufficient detail enable one of ordinary skill in the art to practice the claimed invention without undue experimentation. What appears to be at issue is the Examiner's belief that the claims merely recite the use of any composition possessing a "odor below a detectable threshold".

Applicants respectfully submit that the claimed method is more significantly limited than described in the Official Action and accordingly the claimed invention may be practiced by one of ordinary skill in the art without undue experimentation.

Applicants note, the claims are defined by administration of a class of compounds of terpene alcohols. Terpene alcohols are alcohols of terpene compounds which are constructed of multiples of the 5-carbon hydrocarbon isoprene (2-methyl-1,3-butadiene), terpene compounds containing two isoprene units being called monoterpenes, containing three isoprene units being called sesquiterpenes, and containing 4, 6 and 8 units called diterpenes, triterpenes and tetraterpenes. (See attached passage from *Biochemistry, second edition* by A. L. Lehninger). Applicants note, that the claims have been amended to recite the genus of terpene alcohols based on the Examiner's recognition that the compounds on page 6 includes mono and di-terpene compounds. Applicants have corrected an obvious typographical error, the existence of and appropriate correction thereof being clear to those of ordinary skill in the art *In re Oda*, 170 USPQ 268 (CCPA (1971)). Accordingly, the claims are fundamentally limited to alcohol of terpene compounds.

Secondly, the claimed method is limited in that the terpene alcohol has a boiling point of at least 250°C. Such a recitation further limits the scope of the claimed compounds of

terpene alcohols in a very quantifiable manner. Terpene alcohol compounds in which the boiling point is below 250° are outside of the scope of the claims.

Further, the claimed method is limited to the use of terpene alcohol compounds having an odor below a detectable threshold. Having "an odor substantially below the detectable threshold" is defined on page 7, lines 4-6 of the specification. As such, the claimed method is believed to be sufficient described to enable those of ordinary skill in the art to practice the claimed invention without undue experimentation.

While the Examiner notes that a finite number of examples are set forth in the specification, such finite identification is not *per se* a failure to enable the invention without undue experimentation. Applicants note that all patent specification, which contain examples, only contain a finite number of examples.

However, Applicants note that they have presented working examples and the absence of an infinite number of disclosed compositions does not *per se* fail to provide sufficient working examples. As Applicants have provided working examples as well as an exemplary list of suitable compounds, defining a class of compounds quite narrow in terms of the chemical structure and physical properties thereof, the claimed invention is clearly enabled to those of ordinary skill in the art without undue experimentation.

Moreover, the burden is on the Patent Office to provide reasons based on scientific principles, to doubt the objective enablement of Applicant's claimed invention. Applicant's disclosure must be taken as in compliance with the enabling requirement under 35 USC 112, first paragraph, unless, there is reason to doubt the objective truth of the statements contained therein. (In re Marzocchi, 169 USPQ 367, 369 (CCPA 1971)). In the absence of any reasons provided by the Examiner, withdrawal of the rejection under 35 USC 112, first paragraph is respectfully requested.

Accordingly withdrawal of the rejection under 35 U.S.C. § 112, first paragraph is respectfully requested.

The rejection of claims 1-14 under 35 U.S.C. § 112, second paragraph has been obviated by appropriate amendment.

Applicants have now amended the method claims to recite the specific function of increasing ECG R-R interval, decreasing systolic blood pressure as well as decreasing diastolic blood pressure. The metes and bounds of the claimed invention are clear in view of Applicants' amendment. The attached preprint of Dayawansa et al. from *Autonomic Neuroscience: Basic and Clinical* 477, (2003) identifies the relationship between increasing an ECG R-R interval, decreasing systolic blood pressure, and decreasing diastolic blood pressure with autonomic responses. The attached abstracts of Malliani et al. from *Circulation* (1991 Aug) 84 (2) 482-92 and Pagani et al. from *Circulation Research* (1986 Aug) 59 (2) 178-93 describe relationships between heart rate activity and vagal or sympathetic activity. Withdrawal of the rejection under 35 U.S.C. § 112 second paragraph is respectfully requested.

The rejection of Claim 3 under 35 U.S.C. § 112, second paragraph has been obviated by appropriate amendment.

As noted by the Examiner, some of the enumerated compounds fall outside of the meets and bounds of sesquiterpene alcohol and accordingly Applicants have now amended the claims to recite "terpene alcohol", consistent with the genus of compounds described. Applicants have corrected an obvious typographical error, the existence of and appropriate correction thereof being clear to those of ordinary skill in the art *In re Oda*, 170 USPQ 268 (CCPA (1971)). Accordingly withdrawal of this ground of rejection is respectfully requested.

Applicants submit that this application is now in condition for allowance and early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

Customer Number

22850

Tel: (703) 413-3000  
Fax: (703) 413 -2220  
(OSMMN 08/03)  
RLC:smi

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Norman F. Oblon  
Registration No. 24,618

Richard L. Chinn, Ph.D.  
Registration No. 34,305  
Attorneys of Record